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tissue repair

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0003 '99 JUL 14 A9:14

July 6, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 99D-0557
Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans

Genzyme Tissue Repair wishes to submit the following comments for consideration in response to the draft guideline "Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans" published in the Federal Register on April 6, 1999 (Docket 99D-0557). The guideline seeks to provide guidance to industry on three points:

1. The potential health risks posed by nonhuman primate xenografts
2. The need for further scientific research and evaluation of these risks, particularly infectious agents
3. The need for public discussion concerning these issues.

We agree with the Food and Drug Administration's position that the use of nonhuman primate cells, tissues and organs deserves special consideration. We also agree that the definition in the draft document for use of non-human primate xenografts in humans is appropriate for those materials.

At this time, we would like to state that the definition of xenotransplantation presented in the draft guideline published September 23, 1996 ("Draft Public Health Service Guideline on Infectious Disease Issues in Xenotransplantation"), appropriately encompasses all other products that should be considered xenografts.

Any decision to modify the definition of xenotransplantation presented in the September 23, 1996 guideline will affect a number of other products not currently classified as xenografts. Broadly applying a definition of xenotransplantation would significantly change the regulatory environment for these products, potentially applying unnecessary requirements.

We recognize the effort the Agency has put forth to engage industry on this topic (June 3-4 Biologic Modifiers Advisory Committee). Continued dialogue between the Agency and industry is critical prior to any further expansion of the definition of xenotransplantation or the application of such definition. In this way, the Agency and industry can craft regulation and guidance that protects the public health meets the Agency's stated objective of public discussion regarding the issues associated with xenotransplantation while maintaining a regulatory environment that fosters the development of important and potentially life saving therapies.

Sincerely,



Gregory Dombal
Manager, Regulatory Affairs
Genzyme Tissue Repair

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99D-0557

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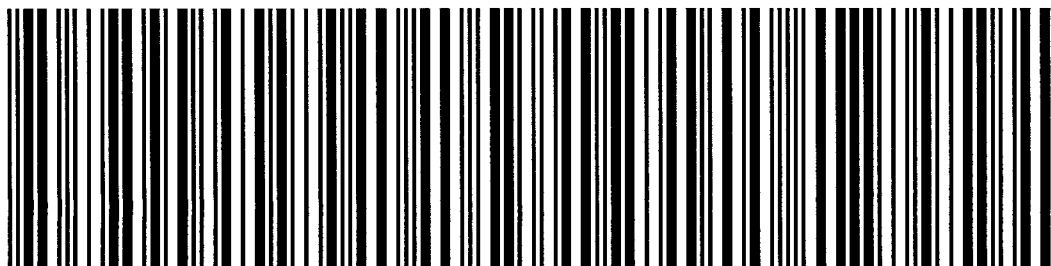
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